IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Jerold S. Horn et al. Art Unit : 1713
Serial No. : 09/262,628 Examiner : Zitomer
Filed : March 4, 1999
Title : FLUOROPOLYMERIC ORTHODONTIC ARTICLE

BOX AF
Commissioner for Patents
Washington, D.C. 20231

#17
12/5

BRIEF ON APPEAL

(1) Real Party in Interest

The real party in interest is 3M Innovative Properties Co., Inc.

(2) Related Appeals and Interferences

None.

(3) Status of Claims

Claims 1-4, 7, 8, 10, and 12-23 are pending, and stand finally rejected.

(4) Status of Amendments

All amendments have been entered.

(5) Summary of Invention

The invention, in general, relates to applicants' discovery that a certain class of fluoropolymers called "fluoroplastics" can be used to make relatively rigid, load-bearing orthodontic articles such as brackets. Previously, ceramics were used to make these articles

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because of their high strength and pleasing aesthetic qualities. Ceramics, however, lacked good stain resistance, causing them to become discolored when contacted with food such as spaghetti sauce or mustard. The use of fluoroplastics provides improved orthodontic articles because the fluoroplastics combine the mechanical strength and aesthetic qualities of ceramics with good stain resistance. The orthodontic articles do not unduly darken or turn yellow during the time the article remains in the oral cavity. In addition, the articles maintain their essentially translucent to transparent character over the useful life of the article such that they transmit the color of the underlying tooth surface to which they are adhered.

(6) Issues

(1) Whether the subject matter of claims 17-19 is novel in view of Hammar et al., U.S. 5,461,133 ("Hammar")?

(2) Whether the subject matter of claims 1-4, 7-8, 10, and 12-23 would have been obvious in view of Hammar combined with Putska, U.S. 4,323,956 ("Putska")?

(3) Whether claims 1-4, 7-8, 10, and 12-23 satisfy the requirements of 35 U.S.C. §112, first paragraph?

(7) Grouping of Claims

Claims 1-4, 7-8, 10, and 12-16 stand or fall together.

Claims 17-23 stand or fall together.

(8) Argument

The outstanding rejections reflect a fundamental misunderstanding of basic concepts relating to polymer science and engineering, particularly as those concepts relate to the classes of polymers known in the art as "fluoroplastics" and "fluoroelastomers." The result is rejections that have no basis in either fact or law, and require reversal. We first present a brief tutorial to familiarize the Board with these concepts. We then address each rejection, and demonstrate how a misunderstanding of these concepts led to the rejection.

A "homopolymer" is a polymer made by polymerizing a single type of monomer. Thus, the final product contains only this type of monomer. Typically, one refers to a homopolymer by

using the prefix "poly," followed by the name of the monomer. Thus, for example, a homopolymer made by polymerizing vinylidene fluoride monomers contains only vinylidene fluoride units and is referred to as "polyvinylidene fluoride."

A "copolymer" is a polymer made by polymerizing together more than one type of monomer. Typically, one refers to a copolymer by reciting the name of each monomer used to prepare the copolymer, followed by the word "copolymer." Thus, for example, a copolymer prepared by polymerizing ethylene and tetrafluoroethylene monomers together is referred to as "ethylene-tetrafluoroethylene copolymer." Such a copolymer contains only these two types of units.

If a third monomer were also used to prepare the copolymer, the name of the copolymer would further include the name of this third monomer. Therefore, a person of skill in this field, seeing the words "vinylidene fluoride-tetrafluoroethylene-ethylene copolymer" would know that this particular copolymer contains units of the three enumerated monomers, and only these monomers. Such a person would also recognize that this copolymer is distinct from an ethylene-tetrafluoroethylene copolymer that, as its name implies, contains only ethylene and tetrafluoroethylene units. It will be important to keep these considerations in mind when we discuss the outstanding rejection of claims 17-23.

Fluoropolymers, as the Polymer Technology Dictionary demonstrates,[1] represent a genus of fluorine-containing polymers that includes two distinct species: fluoroplastics and fluororubbers (also known as fluoroelastomers). The definitions of "fluoroplastic" and "fluororubber" also found in the Polymer Technology Dictionary underscore the fact that these materials represent two different, art-recognized classes of fluoropolymers. As the names imply, one is a plastic, while the other is a rubber. Plastics and rubbers, as is well known, have different chemical and physical properties, and are used in different applications. Recognizing the fact that fluoroplastics and fluoroelastomers are not one and the same, and are not interchangeable, is crucial to understanding how the Examiner erred in rejecting the claims.

[1] An excerpt from the Polymer Technical Dictionary is included as Exhibit 1. Applicants previously included this excerpt of part of their Response mailed 1/7/02. The Examiner agrees that the Polymer Technical Dictionary is an authoritative text in the field of polymer science and engineering.

Claims 17-19 stand rejected under 35 U.S.C. §102(b) over Hammar. A rejection for lack of novelty requires that the prior art reference disclose each limitation of the claim, either expressly or inherently. Furthermore, the rejection requires absolute identity between the reference and the claim. Any deviation precludes the rejection. *Minnesota Mining & Manufacturing Co. v. Johnson & Johnson Orthopedics, Inc.*, 976 F.2d 1559, 1565 (Fed. Cir. 1992). The Hammar patent does not satisfy this standard.

Claim 17 (the independent claim) requires an orthodontic article comprising a fluoroplastic selected from a defined group of seven particular fluoroplastics:[2]

(1) perfluoroethylene-propylene copolymer (a copolymer containing only units derived from two specific monomers: perfluoroethylene and propylene);

(2) perfluoroalkoxyethylene (a copolymer containing units derived from two monomers: tetrafluoroethylene and a vinyl ether);

(3) ethylene-tetrafluoroethylene copolymer (a copolymer containing only units derived from two specific monomers: ethylene and tetrafluoroethylene);

(4) polyvinylidene fluoride (a homopolymer containing only units derived from a single monomer: vinylidene fluoride);

(5) polyvinyl fluoride (a homopolymer containing only units derived from a single monomer: vinyl fluoride);

(6) polychlorotrifluoroethylene (a homopolymer containing only units derived from a single monomer: chlorotrifluoroethylene);

(7) ethylene-chlorotrifluoroethylene copolymer (a copolymer containing only units derived from two specific monomers: perfluoroethylene and propylene).

Claim 17 requires each of these polymers to be a fluoroplastic. This fact alone precludes the rejection based upon Hammar because, as stated explicitly in Hammar, each of the materials described in Hammar is a fluoroelastomer. As discussed above, fluoroelastomers and fluoroplastics represent two distinct, art-recognized classes of fluoropolymers. However, this is not the only difference between Hammar and claim 17. Specifically, and contrary to the

[2] The Examiner, in remarks accompanying the Advisory Action, alleges that claim 17 is a Markush claim. Applicants disagree. Nevertheless, this issue is irrelevant. What matters is that claim 17 indisputably requires particular polymers, none of which is identical to the polymers described in Hammar.

Examiner's assertions, a comparison between the fluoroelastomers listed in Hammar and the fluoroplastics listed in claim 17 reveals that, in terms of the monomer units that make up the various polymers, Hammar's fluoroelastomers are not identical to the fluoroplastics that claim 17 requires.

Hammar, at col. 5, lines 58-67, describes the following three fluoroelastomers:

(1) vinylidene fluoride-hexafluoropropylene copolymer (a copolymer containing only units derived from vinylidene fluoride and hexafluoropropylene);

(2) vinylidene fluoride-hexafluoropropene-tetrafluoroethylene (a copolymer containing units derived from three monomers: vinylidene fluoride, hexafluoropropene, and tetrafluoroethylene);

(3) vinylidene fluoride-hexafluoropropene-tetrafluoroethylene copolymer plus cure-site monomer (a copolymer containing units derived from four monomers: vinylidene fluoride, hexafluoropropene, tetrafluoroethylene, and a cure-site monomer).

None of the copolymers is identical to the seven fluoroplastic polymers listed in claim 17. For one thing, copolymers (2) and (3) are made of three and four types of monomer units, respectively, while the polymers in claim 17 are made from a maximum of two types of monomer units. In addition, each of these copolymers features units derived from vinylidene fluoride and at least one additional monomer. In contrast, the only fluoroplastic listed in claim 17 based upon vinylidene fluoride contains **only** vinylidene fluoride units (i.e., polyvinylidene fluoride homopolymer).

Hammar, at col. 6, also lists a number of patents said to describe suitable fluoroelastomers for Hammar's purposes. According to the Examiner, three of them (U.S. 3,712,877; U.S. 4,882,390; and U.S. 4,035,565) describe polymers identical to the polymers listed in claim 17. Again, however, comparison between the polymers disclosed in the patents and the polymers that claim 17 requires reveals that this is not true.

U.S. 3,712,877, at the paragraph bridging cols. 1 and 2, describes the following fluoroelastomer copolymers:

(1) vinylidene fluoride-chlorotrifluoroethylene copolymer;

(2) vinylidene fluoride-perfluoropropene copolymer;

(3) vinylidene fluoride-perfluoropropene-tetrafluoroethylene copolymer.

Each of these copolymers contains units derived from vinylidene fluoride and at least one additional monomer. In contrast, the only fluoroplastic listed in claim 17 based upon vinylidene fluoride contains **only** vinylidene fluoride units (i.e., polyvinylidene fluoride homopolymer).

In addition, U.S. 3,712,877, at col. 3, lines 41-72, lists a number of monomers from which fluoroelastomer copolymers theoretically could be prepared. However, the only specific polymers described are copolymers based upon vinylidene fluoride and at least one additional monomer. Indeed, the preferred copolymers are identical to the copolymers set forth at cols. 1-2 of the patent and listed above. Clearly, then, it is these copolymers to which the Hammar patent refers as examples of suitable fluoroelastomer copolymers. For the reasons stated above, these copolymers differ from the fluoroplastics required in claim 17, none of which features vinylidene fluoride-derived units in combination with units derived from one or more additional monomers.

The only polymers described in U.S. 4,882,390 are copolymers that contain units derived from three different monomers: vinylidene fluoride, tetrafluoroethylene, and an olefin. None of the polymers listed in claim 17 contains units derived from three different monomer units. Moreover, the only fluoroplastic listed in claim 17 based upon vinylidene fluoride contains **only** vinylidene fluoride units (i.e., polyvinylidene fluoride homopolymer).

U.S. 4,035,565 describes copolymers containing units derived from a minimum of three different monomers, one of which is a cure-site monomer. In contrast, the polymers required in claim 17 contain units derived from a maximum of two different monomers.

Hammar, therefore, clearly fails to describe polymers identical to the particular polymers recited in claim 17. The same is true of dependent claims 18-19. Accordingly, the rejection under 35 U.S.C. §102(b) should be reversed.

Claims 17-23 further stand rejected under 35 U.S.C. §103(a) over Hammar in combination with Putska. This rejection is predicated on the Examiner's mistaken belief that Hammar, the primary reference, describes the particular fluoroplastics that the claims require. Hammar, however, does not even describe fluoroplastics generally, let alone the specific fluoroplastics that the claims require. Although Putska lists a number of number of polymers that would be classified as fluoroplastics, Putska describes using these materials in light fixture windows and lenses.

To determine whether a reference can provide the basis for an obviousness rejection, it is necessary to answer two questions. First, is the reference from the same field of endeavor as the inventor? If not, is it nevertheless relevant to the problem facing the inventor? If the answer to both questions is no, then the reference cannot support an obviousness rejection. *In re Clay*, 966 F.2d 656, 658-59 (Fed. Cir. 1992) (reversing Board of Appeals for upholding obviousness rejection based upon non-analogous art).

Applying this analysis to Putska, the answer, just as in *Clay*, is no. The light fixture windows and lenses that are the subject of Putska are completely unrelated to orthodontics. In addition, Putska is not relevant to the problem facing the applicants, i.e., combining stain resistance with optical properties sufficient for orthodontic applications. Therefore, a person of ordinary skill in the orthodontics field, looking for a material that would combine the mechanical and aesthetic properties of ceramics with good stain resistance in a rigid orthodontic article such as a bracket, would not have looked to Putska to find suitable materials, Putska, therefore, is not properly combinable with Hammar. Accordingly, the subject matter of claims 17-23 would not have been obvious, and the rejection should be reversed.

Claims 1-4, 7-8, 10, and 12-16 also stand rejected under 35 U.S.C. §103(a) over Hammar in combination with Putska. Although these claims do not require the particular polymers set forth in claim 17, each requires the presence of a fluoroplastic polymer for making relatively rigid orthodontic articles such as brackets, just as in the case of claim 17. Such articles must be strong. Fluoroplastics are suitable for making these articles because they combine the mechanical and aesthetic properties of ceramics with good stain resistance. Hammar, on the other hand, describes the use of a different class of polymers (fluoroelastomers) for a different application (making elastomeric orthodontic devices such as force modules that have a resilient force in tension or compression that can be used to move a tooth or an orthodontic appliance relative to other teeth or orthodontic applicances).[3] Hammar teaches nothing regarding fluoroplastics or applications that would require the strength that fluoroplastics provide. Putska does not cure the deficiencies of Hammar because Putska is directed towards materials for use in light fixture windows and lenses—applications completely unrelated to orthodontics. For the

[3] See Hammar, col. 2, lines 37-39.

reasons discussed above, Putska is not properly combinable with Hammar. Thus, claims 1-4, 7-8, 10, and 12-16 would not have been obvious, and the rejection should be reversed.

The Examiner further rejects claims 1-4, 7-8, 10, and 12-23 under 35 U.S.C. §112, first paragraph, focusing on the term "fluoroplastic" that applicants added to the claims by amendment during prosecution. In the Advisory Action, the Examiner states the issue as follows:

> The issue is the difference in the term [i.e., "fluoroplastic" vs. "fluoroelastomer" or "fluoropolymer"] as perceived by applicant and where the alleged difference is enabled in the specification.

We first address the Examiner's point regarding "the difference in the term as perceived by the applicant." We do not fully understand what the Examiner means by the phrase "perceived by the applicant." There can be no question that in the field of polymer science and engineering, the terms "fluoroplastic" and "fluoroelastomer" are used to denote two different classes of fluorine-containing polymers (i.e., "fluoropolymers") having different properties. The Polymer Technology Dictionary, which the Examiner agrees is an authoritative text in the field, conclusively establishes this point. Indeed, if these two materials were one and the same, why would an authoritative text such as the Polymer Technology Dictionary both to distinguish between the two of them? Therefore, as "perceived by the applicant," and everyone else in the field of polymer science and engineering, "fluoroplastics" are different from "fluoroelastomers." The former is a plastic with good mechanical properties needed for devices such as orthodontic brackets. The latter is a rubber that deforms under a mechanical load, and is thus unsuitable for these devices.

We also do not entirely understand the Examiner's next point, i.e., "where the alleged difference in enabled in the specification." To the extent that the Examiner is raising a written description issue, we note that the Background section of the application, for example, establishes that the invention is directed towards plastic orthodontic articles with improved stain resistance. Moreover, the particular plastics described in the application as being useful for this purpose are all classified as fluoroplastics, as shown, for example, in Grootaert, U.S. 5,285,002, which refers to "[f]luoroplastics, particularly polychlorotrifluoroethylene, polytetrafluoroethylene, copolymers of tetrafluoroethylene and hexafluoropropylene, and

poly(vinylidene fluoride) ...."[4] Therefore, a person of ordinary skill in the field of polymer science and engineering, reading the application, would appreciate, from the description of the polymers themselves, and the use for which the polymers were intended, that all of these materials were fluoroplastics. Accordingly, the requirements of §112, first paragraph, are satisfied. *See In re Alston*, 76 F.3d 1168, 1172 (Fed. Cir. 1996) ("the description must allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed") (quoting *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989)).

The Examiner states that the specification does not mention the word "fluoroplastic," and uses this as a basis to justify the application. The Examiner's focus, however, is misplaced. While it is true that the application does not use the word "fluoroplastic," this fact is irrelevant. *See id.* ("In order to meet the adequate written description requirement, the applicant does not have to utilize any particular form of disclosure ....").

Finally, claims 1-4, 7-8, 10, and 12-23 stand rejected under 35 U.S.C. §112, first paragraph, for lack of enablement on the ground that "the specification, while being enabling for specified fluoropolymers and amounts thereof, does not reasonably provide enablement for the multiplicity of polymers and amounts thereof within the claims."[5] At the outset, we note that this rejection cannot possibly apply to claims 17-23 because each of these claims, as discussed, above, requires certain enumerated polymers. Even more fundamentally, however, the rejection cannot stand as applied to any of the claims because it is rooted in the Examiner's misunderstanding of the terms "fluoropolymer," "fluoroplastic," and "fluoroelastomer." When these claims are properly understood, as they would be to a person of ordinary skill in the field of polymer science and engineering, it is apparent that the claims do not cover every conceivable type of fluorinated polymer. For example, the claims do not cover fluoroelastomers.

The specification provides several examples of suitable fluoroplastics for use in the claimed orthodontic articles (see, e.g., pp. 6-7). Commercial sources for these materials are also provided. Furthermore, the specification includes a set of test procedures to help assist in the

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[4] A copy of the Grootaert patent is included as Exhibit 2. Applicants previously provided the Examiner with a copy of this patent in the Response filed 7/18/01. If the Board would find it useful, applicants are willing to provide commercial literature for the fluoroplastics described in the application, which demonstrates that these polymers are indeed classified as fluoroplastics by those in the field.

[5] Office Action mailed 4/18/01, p. 2.

selection of an appropriate fluoroplastic for making the article. The test procedures provide methods for assaying the stain resistance and transmittance level of a material. Finally, the specification includes numerous examples to demonstrate how the described fluoroplastics could be selected, prepared, and tested. The specification, therefore, provides sufficient information so that a person of ordinary skill could make the orthodontic articles of the current invention. Accordingly, the rejection cannot stand and should be reversed.

The brief fee of $320 is enclosed. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 11/5/02

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Appendix of Claims

1. An orthodontic article comprising a fluoroplastic, said article exhibiting at least about 0.001% transmittance at 546 nm when measured according to the Transmittance Test Procedure.

2. The article of claim 1, wherein said article exhibits a transmittance of at least about 0.001% over a wavelength range of from 400 nm to 800 nm when measured according to the Transmittance Test Procedure.

3. The article of claim 1, wherein said article exhibits a Delta E color shift of no greater than about 2 when tested according to the Hydrophilic Color Shift Test, and a Delta E color shift of no greater than about 5 when tested according to the Oleophilic Color Test.

4. The article of claim 1, wherein said fluoroplastic is selected from the group consisting of perfluoroethylene-propylene copolymer, perfluoroalkoxyethylene, ethylene-tetrafluoroethylene copolymer, polyvinylidenefluoride, polyvinylfluoride, polychlorotrifluoroethylene, ethylene-chlorotrifluoroethylene copolymer, or a combination thereof.

7. The article of claim 1, wherein said fluoroplastic comprises ethylene-chlorotrifluoroethylene copolymer.

8. The article of claim 1 wherein said article comprises an orthodontic bracket.

10. The article of claim 1, wherein said article exhibits at least about 0.01% transmittance at 546 nm when measured according to the Transmittance Test Procedure.

12. A method for using an orthodontic bracket, said method comprising:

contacting a fluoroplastic orthodontic bracket having an average transmittance of at least 0.001% when measured according to the Transmittance Test Method with a composition comprising an organoborane compound; and

adhering said bracket to a tooth.

13. The method of claim 12, wherein said fluoroplastic orthodontic bracket exhibits a Delta E color shift of no greater than about 2 when tested according to the Hydrophilic Color Shift Test, and a Delta E color shift of no greater than about 5 when tested according to the Oleophilic Color Shift Test.

14. The method of claim 12, wherein said fluoroplastic article comprises a fluoroplastic selected from the group consisting of perfluoroethylene-propylene copolymer, perfluoroalkoxyethylene, ethylene-tetrafluoroethylene copolymer, polyvinylidenefluoride, polychlorotrifluoroethylene, ethylene-chlorotrifluoroethylene copolymer, or a combination thereof.

15. The method of claim 12, further comprising

contacting said surface comprising an organoborane compound with a polymerizable composition, and

polymerizing said polymerizable composition to form an adhesive composition.

16. The method of claim 12, further comprising

contacting a polyimide film with said composition comprising an organoborane compound prior to adhering said bracket to a tooth.

17. An orthodontic article comprising a fluoroplastic selected from the group consisting of perfluoroethylene-propylene copolymer, perfluoroalkoxyethylene, ethylene-tetrafluoroethylene copolymer, polyvinylidenefluoride, polyvinylfluoride, polychlorotrifluoroethylene, ethylene-chlorotrifluoroethylene copolymer, or a combination thereof.

18. The article of claim 17, wherein said article comprises a bracket.

19. The article of claim 17, further comprising a metallic component.

20. The article of claim 17, wherein said article exhibits a Delta E color shift of no greater than about 2 when tested according to the Hydrophilic Color Shift Test, and a Delta E color shift of no greater than about 5 when tested according to the Oleophilic Color Shift Test.

21. The article of claim 17, wherein said article exhibits at least about 0.001% transmittance at 546 nm when measured according to the Transmittance Test Procedure.

22. The article of claim 17, wherein said article exhibits at least about 0.01% transmittance at 546 nm when measured according to the Transmittance Test Procedure.

23. The article of claim 17, wherein said article exhibits at least about 0.001% transmittance over a wavelength range of from 400 nm to 800 nm when measured according to the Transmittance Test Procedure.